

EXHIBIT "II"

RECEIVED

REPORT TO OPMC REGARDING [REDACTED] C[REDACTED], M.D.

Case CR [REDACTED] R[REDACTED] J[REDACTED]

APR 19 2011

OFFICE OF PROFESSIONAL
MEDICAL CONDUCT

I have reviewed all the documents presented to me regarding the above mentioned case.

CLINICAL SUMMARY

Mr. P[REDACTED] J[REDACTED] presented to Dr. C[REDACTED] office for evaluation of possible Lyme disease on 8/11/09.

He had a prolonged history of over a year with complaints of headache, fatigue, memory loss, myalgias, back and neck pain.

He had an active history of bi-polar disorder, and was under the care of a psychiatrist. Additional history included a rash on his chest described as a bull's eye lesion sixteen (16) years previously, and was treated for Lyme disease at that time with a month of oral antibiotics, without any reported secondary manifestations.

He was living in an urban environment, Providence, R.I., not an endemic area for Lyme disease, but reported vacationing in other known endemic areas of coastal New England. At the time of his initial encounter with Dr. C[REDACTED], he reported no tick bite, rash or symptoms other than mentioned above.

Diagnostic evaluation by a neurologist included a negative MRI and MRA of the brain.

His initial physical exam was performed by Diana Waxler in Dr. C[REDACTED] office, and was without any notable findings. Of note, no formal neurologic exam is performed.

A complete laboratory investigation is done, and all serologic studies for Ehrlichia, Babesia, Bartonella are negative. A Lyme screening test was negative, and Western Blot testing revealed a fully negative IgG result, and only a solitary IgM band (p41), which is non-diagnostic by CDC criteria for Lyme disease.

Despite the negative laboratory results, the patient is given a diagnosis of Lyme disease, with an explanation that the testing is most likely non-supportive, perhaps because of a one month treatment course with the antibiotic doxycycline, prescribed for acne, in 2007.

Over the following thirteen(13) months, Mr. J[REDACTED] is subjected to a continuing, escalating combination of multiple oral, and eventual intravenous antibiotics until September 2010.

ANTIBIOTIC THERAPY PRESCRIBED BY DR. CAMERON

Initial therapy prescribed (prior to laboratory results):

- 8/11/09 Amoxicillin 1000 mg tid (twice the recommended dose for suspected/proven Lyme disease) initially for 30 days.

- 11/6/09 Azithromycin 250 mg added to amoxicillin.

- 12/31/09 Doxycycline 300 mg/day (100 mg more than the recommended daily dose), added to the above two antibiotics.

- 2/2/10 Due to gastrointestinal side effects, the doxycycline is discontinued and cefuroxime 500 mg bid is substituted. Patient remains on three oral antibiotics.
- 3/1/10 Dr. C [REDACTED] initiates intravenous antibiotics due a lack of resolution of symptoms on the six (6) month regimen of oral antibiotics (please see my comments regarding his request for approval of I.V. antibiotics).
- 4/29/10 Atovaquone, an anti-parasitic compound with no FDA approval for the treatment of Lyme disease, is added to the now-four (4) drug regimen.
- 5/21 Patient complains of possible side effects from atovaquone, but it is not discontinued at this time.
- 8/10/10 Patient remains on IV ceftriaxone, atovaquone and azithromycin, and is now prescribed rifampin, an antibiotic without FDA approval for Lyme disease, and with known drug-drug interactions with one of Mr. J [REDACTED] other neurologic medications, valproic acid (depakote). Dr. C [REDACTED] office gives the patient the prescription for rifampin, and only then proceeds to check with the psychiatrist who reportedly informs Dr. C [REDACTED] office that "depakote would not have a negative reaction with rifampin", despite the well-known interaction that leads to a less therapeutic level of valproic acid with the co-administration of rifampin.
- Subsequent, sequential valproic acid levels fall to 34.5 and 31.3 (50-100 therapeutic range) in the ensuing two weeks. Not clear from records what information is transmitted to the patient or psychiatrist.
- Intravenous and oral antibiotic combination therapy continues until 9/28/10- a full seven months of IV therapy, and thirteen months of total antibiotics.

CLINICAL ASSESSMENTS, RECORD DOCUMENTATION and LAB RESULTS

I made a thorough review of each patient encounter, and laboratory result in Dr. C [REDACTED] records. The following issues are noteworthy:

- Despite the patients complaints of chronic headache, and cognitive issues, there is never any consideration given, or offer made to do a spinal fluid examination to formally investigate neurologic Lyme disease. This is the standard of care for the diagnosis, and subsequent treatment of neuroborreliosis.
- Despite complaints of joint pain, there is never a formal joint examination in the medical record.
- There is clearly a "template" medical record for both patient history and the multiple physical exams that are purportedly being done in Dr. C [REDACTED] office by multiple examiners. For example, there is a documented exam of the head and neck on 11/6/09 that reportedly describes a "normal larynx, true/false vocal cords, epiglottis". Such an exam can only be done under direct endoscopic examination, and would clearly never be done in an office by the physician-extenders (nurse, ?PA). This exact exam, along with a templated exam of the respiratory and cardiac systems, is documented, and I would note, signed off by Dr. C [REDACTED] over each and every subsequent visit after it appears in the record until 9/28/10.

- There is never any documentation in the record that abnormally low potassium levels are called to the patient on 5/25/09, 6/1/09, 6/14/09. The patient is seen in the office in the interim, and no mention is made of these results. There are notations in the chart that labs are reviewed with patient and all WNL (within normal limits).

REQUEST FOR IV THERAPY AND NIH EVIDENCE

"I consider a course of 4 weeks of IV Rocephin a medical necessity to resolve the remaining symptoms and prevent the severe manifestations of Lyme disease described in recent NIH trials".

This was the closing line of a letter sent on 1/19/10 as part of Dr. C [REDACTED] request from the patient's insurance company to approve intravenous ceftriaxone for what was being referred to as neurologic Lyme disease. I have included a summary of "recent NIH trials" as an attachment to this report. Dr. C [REDACTED] comments are misleading and completely misrepresents the findings of the NIH trials in regards to the benefit of long standing intravenous antibiotics in the treatment of Lyme disease. In fact, the three long term, placebo-controlled trials that were funded by the NIAID of NIH for Post Lyme Disease Syndrome (PLDS) failed to find any benefits with long term intravenous antibiotic treatment, but did prove harmful side effects from the antibiotics.

It must be pointed out that these trials included only patients with well-documented Lyme disease, not suspected Lyme. Lastly, as part of the longest treatment study (10 weeks of I.V. therapy), repeated cognitive testing was performed to elicit any benefit from the treatment - never was any level of sophisticated neuro-cognitive testing done by Dr. C [REDACTED] or his staff, over seven (7) months of I.V. therapy, or the thirteen (13) months of poly-antibiotic treatment.

CONCLUSIONS

Please refer to my thorough description of the CDC criteria for the diagnosis and treatment of Lyme disease as provided in the previous exhaustive review of Dr. C [REDACTED] records submitted in March 2010.

Dr. C [REDACTED] failed to meet the standard of care for the diagnosis of Lyme disease in any of its' manifestations. The patient had no objective physical findings documented to prove any stage of Lyme disease, and his serologic testing was not supportive of the diagnosis of this disease. The standard of care in the investigation of chronic headache, cognitive dysfunction, and any features suggestive of late neurologic Lyme disease should include a cerebral spinal fluid analysis (spinal tap), a test that is never considered in the medical record of this patient.

Dr. C [REDACTED] failed to meet the standard of care in treatment of Lyme disease by prescribing multiple, non-FDA approved antibiotics in a step-wise, additive fashion over a thirteen (13) month period, without any objective evidence of Lyme disease. He failed to follow evidence-based medicine findings from well designed placebo-controlled trials that were initiated by the NIAID of NIH, that do not support long term antibiotic therapy for Lyme disease.

Dr. C [REDACTED] office records are fraught with template driven physical exam findings that could not possibly be found in an internist's office. In addition, the assessment and plans are also templated without regard to any potential consideration of a change in therapy during a prolonged number of follow up visits - this would impress any reviewer of Mr. J [REDACTED] medical record that there was a single strategy only in his care, namely to forge ahead with as many antibiotics, for as long as possible, regardless of evidence or potential side effects.

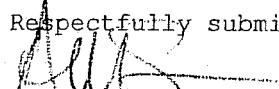
Abnormal laboratory findings were not reported to the patient in a timely fashion (if ever), and no therapeutic interventions were made in regards to low serum potassium results in May and June 2009.

Well known drug-drug interactions were not considered appropriately when rifampin (a non-FDA approved treatment for Lyme) was added to Mr. J [REDACTED] regimen that included the neurologic agent, valproic acid. Any internist would be well aware of this interaction, and would not rely on an approval from a psychiatrist. Subsequently, Mr. J [REDACTED] valproic acid levels became sub-therapeutic, as predicted, but not prevented.

Dr. C [REDACTED] provides misleading interpretations of evidence based medicine in an attempt to gain approval of I.V. antibiotic therapy from Mr. J [REDACTED] health insurance company. In fact, there was no substantial evidence that this treatment was indicated, and moreover, the patient did not even have well-documented Lyme disease. This would be considered a serious deviation from the expectation of physician integrity in the presentation of medical evidence.

In conclusion, these deviations from the standard of care in the diagnosis, treatment, monitoring of a patient are considered severe in the context of the overall care of Mr. J [REDACTED]. I would add that my review of medical records of this patient in regards to the physical examinations purportedly being done at numerous monthly follow up visits raise serious questions as to the actual exams and supervision by Dr. Cameron of his extended staff.

Respectfully submitted,


Alan Sanders, M.D.

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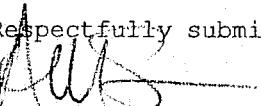
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